Clinical Insights

SUMMARY OF SURVEY DATA

DELIVERING CONFIDENCE FOR ASO AND PFO CLOSURE

REAL WORLD EXPERIENCE WITH THE AMPLATZER™ TREVISIO™ DELIVERY SYSTEM FOR CLOSURE OF ASD AND PFO

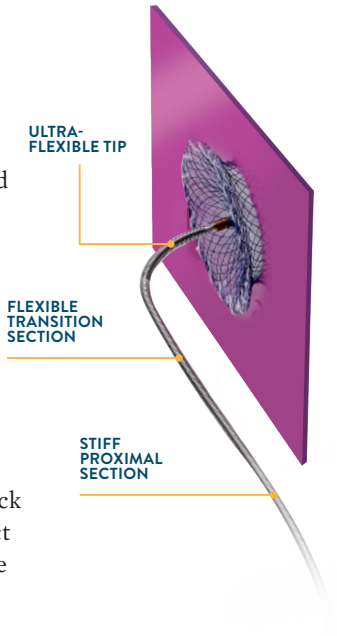
SUMMARY

The Trevisio Customer Feedback Survey collected user feedback from 145 PFO closure procedures and 88 ASD closure procedures utilizing the Amplatzer Trevisio Intravascular Delivery System. During these procedures the Trevisio system was used for delivery of Amplatzer Septal Occluders, Cribriform Occluders and PFO Occluders. Device delivery with the Trevisio system was successful in 99.1% of the cases. From 86% of the procedures assessment of the final device position was reported to be improved compared to the Amplatzer TorqVue Delivery System. Averaged ratings for flexibility and pushability of the Trevisio system were between 'above average' and 'excellent'. Respondents considered the system 'somewhat better' to 'significantly better' compared with regularly used delivery systems. No complications related to the use of the Trevisio system occurred in any of the procedures.

INTRODUCTION

The Amplatzer Trevisio Intravascular Delivery System is an ultra-flexible delivery system for delivery of devices within the chambers and coronary vasculature of the heart. It leverages the one-piece cable design utilized by the Amplatzer TorqVue Delivery System.

The Trevisio delivery cable is comprised of a stiff proximal section, a flexible intermediate transition section and an ultra-flexible tip. This design is intended to provide the required pushability, stability and torque strength with no compromise on sheath diameter. The ultra-flexible tip section is designed to reduce bias on the device and improve the assessment of device position before releasing the cable.



The Trevisio Customer Feedback Survey was conducted to collect real-world user feedback on the Trevisio system when used for implantation of Amplatzer ASD and PFO occluders. Special attention was given to specific improvements implemented in the design of the Trevisio system, such as flexibility, pushability, and assessment of device position.

METHODS

The Trevisio Customer Feedback Survey was conducted between May and September 2020 across 17 countries to collect data from the first cases performed in each of the participating centers (see Table 1). The survey collected procedural data using a survey questionnaire, to be completed per individual ASD or PFO closure procedure utilizing the Trevisio system. Collected data included the type of procedure, the Trevisio system, sheath size and Amplatzer occluder used, successful use of the device, performance ratings for the Trevisio system, and any complications related to the Trevisio system.

TABLE 1: COUNTRIES PARTICIPATING IN THE TREVISIO CUSTOMER FEEDBACK SURVEY

Austria	Israel
Belgium	Netherlands
Canada	New Zealand
Finland	Norway
France	Poland
Germany	Spain
Greece	Switzerland
Ireland	United Kingdom
Italy	United States

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PROCEDURES AND DEVICES

In total, 233 cases were documented, including ASD closure in pediatric patients (48 cases), ASD closure in adults (40 cases), and PFO closure (145 cases). For almost all procedures (n=223) the 80 cm Trevisio system was used. The 60 cm device was only used in 6 ASD closure procedures in pediatric patients (device length was not recorded in 4 procedures). In 1 procedure involving closure of 2 septal defects, 2 delivery systems were used.

Devices delivered by the Trevisio system included the Amplatzer Septal Occluder (9-ASD-0XX), Amplatzer Cribriform Occluder (9-ASD-MF-0XX) and Amplatzer PFO Occluder (9-PFO-0XX) (see Figure 1). All 11 Cribriform Occluders documented by the survey were used for PFO closure. In 2 cases, a PFO occluder was used to close an ASD. Various device sizes of the ASO device, ranging from 8 – 36 mm were used. Among the PFO occluders, the 25 mm device was used in 80% of the cases. As the majority of procedures involved PFO closure, 8F and 9F sheaths were used most frequently (80% of all cases). Of the 17 procedures using a 10F sheath, 8 cases involved the delivery of a PFO occluder (25 mm: n=3, 35 mm: n=5).

PROCEDURAL PERFORMANCE

Successful device delivery with the Trevisio system was reported in 99.1% of 230 documented cases. Device delivery was not successful in 2 cases, including 1 ASD closure procedure in an adult patient and 1 PFO closure procedure. In all documented cases it was reported that the delivery system could successfully be withdrawn.

In 74% of the cases, the marking on the delivery cable, indicating that the occluder is nearing the end of the sheath, was considered to be helpful. A positional adjustment or shift in the device position upon removal of the delivery cable was noticed in 51% of the cases (ASD closure in pediatric patients: 47%, ASD closure in adults: 53%, PFO closure: 52%). In 87% of the procedures, the Trevisio Intravascular Delivery System was reported to improve the assessment of the final device position, compared to the Amplatzer TorqVue Delivery System (ASD closure in pediatric patients: 96%, ASD closure in adults: 90%, PFO closure: 83%).

On average, the flexibility and pushability of the delivery cable of the Trevisio system were rated between 'above average' and 'excellent' (mean score of 4.6 and 4.1 for flexibility and pushability, respectively on a scale from 1 (poor) to 5 (excellent), see Figure 2). In 80% of the cases, the Trevisio system was considered 'somewhat better' or 'significantly better' than the delivery system typically used by the survey respondents (with a 'somewhat better' or 'significantly better' rating in 91%, 85% and 74% of cases involving ASD closure in pediatric patients, ASD closure in adults and PFO closure, respectively). A mean comparative score of 4.2 was achieved on a scale from 1 (significantly worse) to 5 (significantly better, see Figure 3). Most of the survey respondents were regular users of the TorqVue delivery system.

SAFETY

All 233 procedures performed with the Trevisio Intravascular Delivery System were completed without device-related complications. The absence of any complications related to the Trevisio system was explicitly documented for all procedures.

KEY CUSTOMER FEEDBACK ON TREVISIO INTRAVASCULAR DELIVERY SYSTEM

- Successful device delivery: **99.1%**
- Positional adjustment / shift in device position upon removal of cable: **51%**
- Trevisio Intravascular Delivery System improved assessment of final device position: **87%**
- Mean ratings on a scale from 1 (poor) to 5 (excellent):
  - Cable flexibility: **4.6**
  - Cable pushability: **4.1**
- Mean comparative performance relative to typically used device on a scale from 1 (significantly worse) to 5 (significantly better): **4.2**
- Rated somewhat or significantly better than the typically used device in **80%** of the cases.
- Trevisio-related complication rate: **0%** (no complications related to the Trevisio system in any of the 233 procedures)

FIGURE 1. TYPE OF PROCEDURE

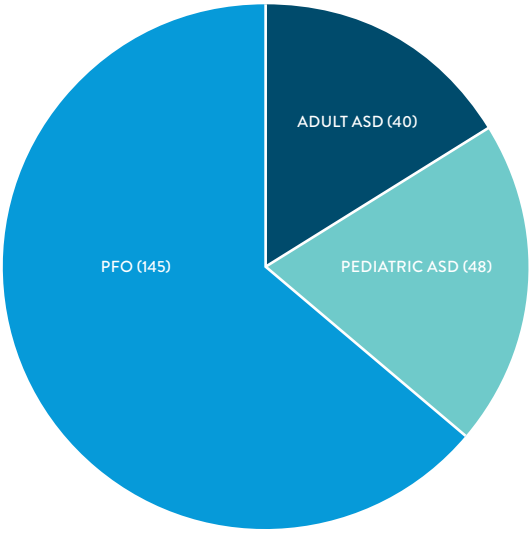

FIGURE 2. OCCLUDERS USED

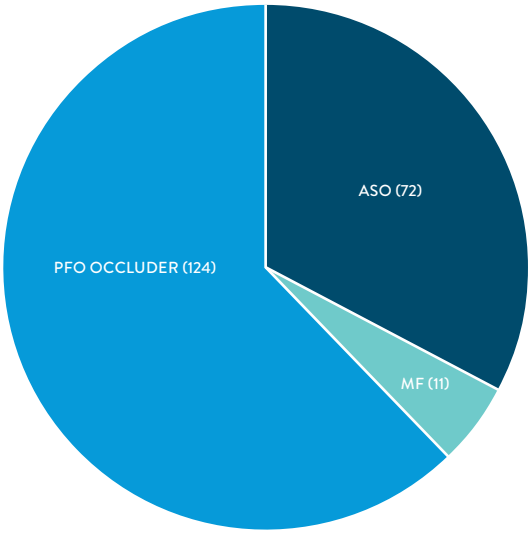

FIGURE 3. SHEATH SIZE PER TYPE OF PROCEDURE

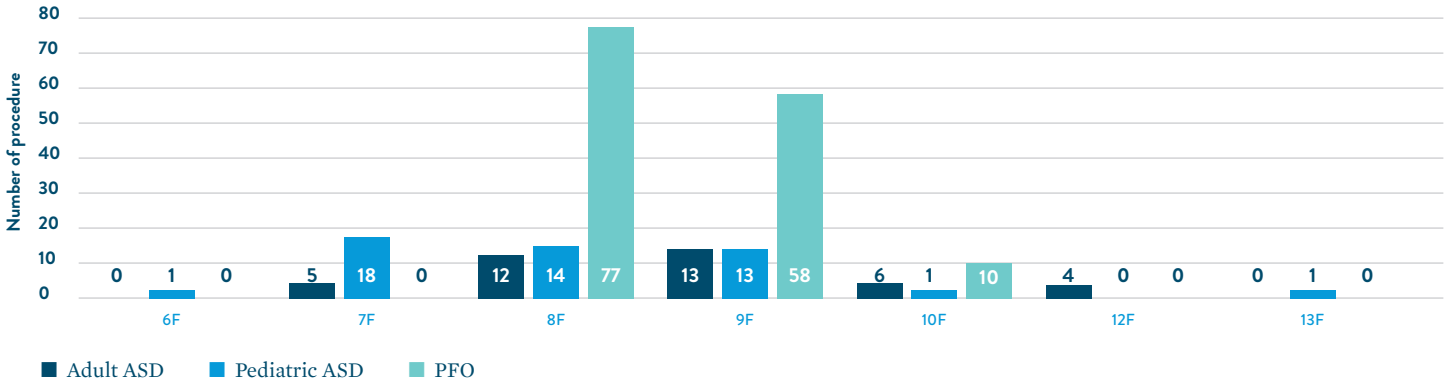

Figure 1: Procedures, implanted occluders and sheath sizes. Numbers represent the number of procedures or devices.
The implanted occluder was not documented in 26 cases, explaining the apparent discrepancy between the number of device types and procedures.

FIGURE 4. CABLE RATINGS

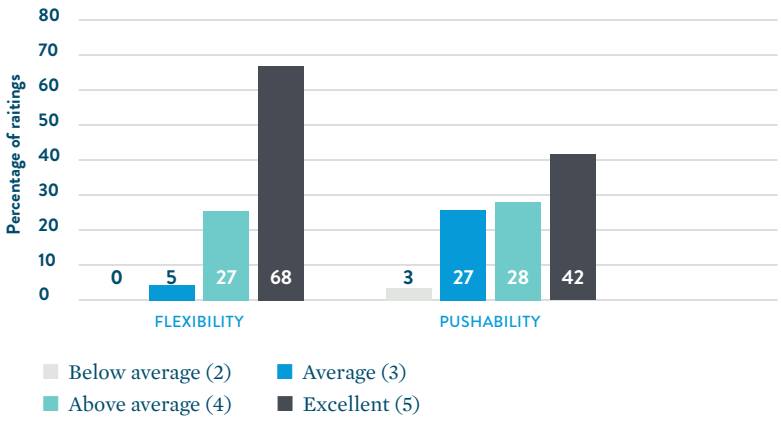

Figure 2: Ratings for cable flexibility and pushability (including all adult/pediatric ASD closure and PFO closure procedures, not recorded in 1 case).

FIGURE 5. COMPARATIVE TREVISIO EXPERIENCE

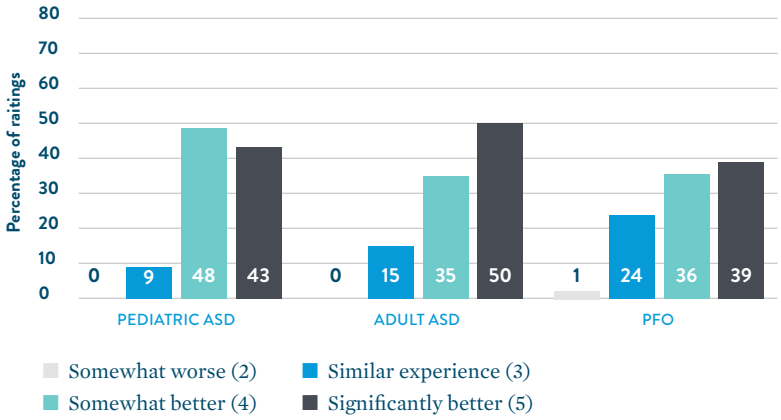

Figure 3: Experience with the Trevisio Intravascular Delivery System compared with the product typically used (not recorded in 2 cases).

CONCLUSION

The Trevisio Intravascular Delivery System is safe for use as delivery system for Amplatzer PFO and ASD occluders. Typical performance is rated as “above average” to “excellent” and, compared to the TorqVue system, as similar to significantly better.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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